JUN 2 4 2002 K020205

510(k) Summary Statement

Date Prepared: June 12, 2002

Submitter's Name/Address: Getinge/Castle Inc.
1777 East Henrietta Road
Rochester, NY 14623

Contact Person: Karla Byrne, Operations Director, Consumable Products Dept.
Telephone: (585) 272- 5007

Trade Name: Castle® SPOR-TEST PA Biological Indicator Kit (K020205)

Classification: Sterilization Process Indicator - 21 CFR 880.2800 (a)
Class II

Predicate Devices: Steris® Process Biological Indicator Kit (K960570)
MDT Unispore® and Spor-Test Biological Indicator (K960777)

Device Description:

The Castle® SPOR-TEST PA Biological Indicator Kit is exclusively intended to monitor the Steris® System 1 peracetic acid sterilization process, with Steris 20 sterilant. The product contains chromatography paper strips that are inoculated with Bacillus stearothermophilus (or G. stearothermophilus) spores at a nominal population of 10^5 per strip. Sterile tubes of Castle Culture Media (modified soybean casein broth) and a transfer clip are included. The materials of construction are equivalent to the Unispore® product. The product is intended to be used in an identical manner as the Steris® Process Biological Indicator Kit.

Intended Use:

The Castle® SPOR-TEST PA Biological Indicator Kit is only intended to monitor the Steris System 1 liquid chemical sterilization system, with Steris 20 sterilant. Use in monitoring other sterilization processes is contraindicated. Castle SPOR-TEST PA Biological Indicators are qualified using Castle Culture Media. When tested at 1,000 ppm peracetic acid, 50°C, the Castle SPOR-TEST PA Biological Indicator will survive at 41 seconds and will be killed at 6 minutes.

Comparison to the Predicate Device: Steris® Process Biological Indicator Kit

- Both devices are exclusively used to monitor the Steris® peracetic acid process.
- Both devices are assessed in process conditions of 1000 parts per million peracetic acid at 50°C.
- Both devices use a chromatography paper carrier inoculated with 10^5 B. stearothermophilus spores.
- Both devices are processed in the Steris® System 1 sterilizer when held by a tension clamp.
- Both devices are open-loop biological indicators that are recovered in tubes of sterile growth medium that uses phenol red as a color change indicator.
- Both devices may only monitor sterilization efficacy on exterior surfaces to loads processed in the Steris® peracetic acid process.

Conclusion:

The Castle® SPOR-TEST PA Biological Indicator Kit is substantially equivalent the Steris® Process Biological Indicator Kit for monitoring the Steris ® System 1 peracetic acid process.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2002

Mr. Mark N. Smith
Director, Corporate QA/RA
Getinge/Castle, Incorporated
1777 East Henrietta Road
Rochester, New York 14623-3133

Re: K020205
Trade/Device Name: Castle ® SPOR-TEST PA Biological Indicator Kit
Regulation Number: 880.6880
Regulation Name: Steam Sterilizer
Regulatory Class: II
Product Code: FRC
Dated: April 8, 2002
Received: April 10, 2002

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Date: **06/17/02**

510(k) Number: K020205

Device Name: **Castle® SPOR-TEST PA Biological Indicator Kit**

Indications for Use:

The Castle ® SPOR-TEST PA Biological Indicator Kit is only intended to monitor the Steris System 1 liquid chemical sterilization system, with the Steris 20 sterilant. Use in monitoring other sterilization processes is contraindicated.

Castle SPOR-TEST PA Biological Indicators are qualified using Castle Culture Media. When tested at 1,000 ppm peracetic acid, 50°C, the Castle SPOR-TEST PA Biological Indicator will survive at 41 seconds and will be killed at 6 minutes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K020205